



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

**MEMORANDUM**

**DATE:** January 21, 2022

**SUBJECT:** Efficacy Review for **CONCROBIUM MOLD CONTROL PLUS**  
EPA Reg. No. 82552-3  
Action Code Case No. 00321941  
E-Submission #67626

**FROM:** César E. Cordero  
Efficacy Branch  
Antimicrobials Division (7510P)  
Date Signed: January 11, 2022

**THRU:** Sophie Nguyen, Team Lead  
Efficacy Branch  
Antimicrobials Division (7510P)  
Date Signed: January 21, 2022

**TO:** Terria Northern, RM 34  
Regulatory Management Branch II  
Antimicrobials Division (7510P)

**APPLICANT:** RUST-OLEUM CORPORATION (formerly Siamons International, Inc.)

**Formulation from the Label:**

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Sodium Carbonate.....	1.00%
<u>Other Ingredients</u> .....	99.00%
<b>Total</b> .....	100.00%

## I. BACKGROUND

**Product Description (as packaged, as applied):** Ready-to-Use Spray

**Submission type:** Label Amendment

**Currently registered efficacy claim(s):** Broad spectrum disinfectant (bactericidal) on hard, non-porous surfaces, fungistat/mildewstat on hard, porous and non-porous surfaces and on cotton fabric surfaces.

**Requested action(s):** Label amendment to add mildewstat/fungistat claims on hard, porous surfaces (wood) for up to 7 days, against *Aspergillus niger* and *Penicillium variable*. Adding use directions for “fogging pre-clean/pre-treatment”.

### Documents considered in this review:

- Cover letter from applicant to EPA dated 9/10/2021
- Proposed label dated 09/10/2021
- Data Matrix (EPA Form 8570-35) dated 9/10/2021
- 1 efficacy study (MRID 51679701)
- Confidential Statement of Formula (EPA Form 8670-4) dated 6/26/2019

## II. PROPOSED DIRECTIONS FOR USE

### DIRECTIONS FOR USE

[Concrobium Mold Control Plus [insert brand name] [this product] [kills] [eliminates 99.9% of] [inhibits1] [or] [and] [prevents1] [is effective against] mold [and] [mildew] [organisms] [growth] on hard non-porous building materials. [Concrobium Mold Control Plus [insert brand name] [this product] [It] [also] [inhibits1] [or] [and] [prevents1] [is effective against] mold [and] [mildew] organisms [growth] on [both][hard][non-porous][and][fabric][porous] [wood,] [wallboard,] [concrete,] [masonry (cinder) block,] [fabric] [and] [building materials] that have been subjected to [moist or] wet environments.] Before applying [this product], remove visible mold growth and correct conditions favorable to mold growth.]

[Concrobium Mold Control Plus [insert brand name] [this product] is suitable for use on [both] hard non-porous [porous] [and] [fabric3] surfaces. [If in doubt,] [Perform a] [Test on a small], [inconspicuous] section. Wipe materials vulnerable to water marks immediately after contact with Concrobium Mold Control Plus [insert brand name] [this product]. Over-application may result in residue formation, which can be easily wiped away with a wiped away with a [Concrobium Mold Control Plus [insert brand name] [dampened cloth] [cloth dampened with the product].]

[Remove visible soil prior to application. [Mold stains may remain visible following treatment.] [This is normal] [In this case] [If so] [If mold stains remain] [following treatment] [reapply] [product] [and] [wipe] [or] [scrub] [area] [away stains] [In some cases, staining may be irreversible.] [[Do not expect] [Concrobium Mold Control Plus [insert brand name] [this product] [to] [will not] [whiten] stains [on contact]]. [If, [following treatment], additional steps are taken to [remove] [or ] [cover] [address] [treat] the [mold] stain, reapply [[Concrobium Mold Control Plus

[insert brand name] [this product]] as a final step [as] [per] [as indicated in] [the] [Preventative Treatment] [To Prevent] [of] [[mold] [and] [mildew] section] [to protect area from regrowth.]]

To clean: Apply [Concrobium Mold Control Plus [insert brand name] by hand-spray, [electric or compression sprayer].

To prevent (inhibit) (control) mold and mildew (and) (or) (disinfect): Apply [Concrobium Mold Control Plus [insert brand name] [this product] by hand-spray [electric or compression sprayer], Expect 350-2800 sq. ft. of surface coverage per gallon depending on surface type [and application method].

[For use [on, in]: {select one or more of the surfaces and use sites from page 7-8}]

### **PREVENTATIVE TREATMENT [FOR] [TO PREVENT] [OF] [MOLD] [AND] [MILDEW]**

To [inhibit] [prevent] mold and mildew growth on hard, non-porous surfaces [and fabrics3]:  
{numbering of steps is optional}

[1)] Clean surfaces.

[2)] Apply [product] [Concrobium Mold Control Plus [insert brand name]] on area until evenly wet.

[3)] [[If desired][If dry time][If water staining][is a] [potential] [concern] [To promote drying] [and] [to][avoid residue marks], [use a] [clean cloth] [or] [paper towel] [dampened with [product] Concrobium Mold Control Plus [insert brand name]] [to] [wipe] [off] [wipe off] [clean] [clean off] [off excess wetness] [with a clean cloth or paper towel].

[4)] Allow treated surfaces to dry completely. [The product generally dries within 2 hours and may take up to 24 hours depending on surface absorbency, temperature and [drying] conditions.]

[[5)] [If treated surfaces are to be [cleaned] [and] [/] [or] [painted], allow [product] [Concrobium Mold Control Plus [insert brand name]] to dry for 24 hours.]

### **REMEDIAL TREATMENT [TO] [REMEDiate] [OF] MOLD [AND] [MILDEW]**

Concrobium Mold Control Plus [insert brand name] must be used as part of a comprehensive mold

remediation or water damage restoration program, [including] [this should also include]:

- Monitor[ing] for conditions favorable to mold growth such as [moisture ingress] [moisture] [water leaks] [flooding] [and] [high relative humidity] [and] [or] [condensation]
- Eliminate [Eliminating] [Correct[ing]] conditions favorable to mold growth
- Dry[ing] affected areas to below 20% moisture content

[[This product] Concrobium Mold Control Plus [insert brand name] must come in direct contact with mold [and] [mildew] to be effective.]

When water damage is suspected, first [eliminate] [correct] the water source. Next, remove excess water and dry surfaces thoroughly. [This product] [Concrobium Mold Control Plus] [insert brand name] can be used on materials removed for disposal. If excess water is removed within 24 hours and hard, nonporous surfaces or fabrics3 surface isare thoroughly dried, spraying affected surfaces with Concrobium Mold Control Plus [insert brand name] [this product] will [inhibit1] [prevent1] [mold] growth. [Structural members and/or contents] [Building materials] exposed to water in excess of 24 hours may have extensive microbial growth that is not visible.

Prepare a complete assessment and remediation plan to incorporate the use of Concrobium Mold Control Plus [insert brand name] [this product].

### III. STUDY SUMMARIES

<b>1.</b>	<b>MRID</b>	<b>51679701</b>
<b>Study Objective</b>		EPA Wood Block Mildew-Fungistat
<b>Testing Lab; Lab Study ID</b>		Analytical Lab Group-Midwest; A32169
<b>Experimental Start Date</b>		02/22/2021
<b>Study Completion Date:</b>		07/23/2021
<b>Test organism(s)</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4+		<i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)
<b>Test Method</b>		Subdivision G – Sec 93-30; Item 4. (Protocol No. SIA001100920.MSTAT)
<b>Application Method</b>		RTU Spray (each side of the carrier was treated by applying the product as a spray using 1 spray from a 12 inches (1 foot) distance, until thoroughly wet. The carriers were subsequently lightly sprayed with the two fungi conidial suspensions using 3 sprays per side of the carrier using a DeVilbiss atomizer.
<b>Test Substance Preparation</b>	<b>Name/ID</b>	CMC-Plus
	<b>Lots</b> <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 2 <input type="checkbox"/> 3	ROJH01102020-A and ROJH01102020-B
	<b>Preparation</b>	<b>Tested concentration:</b> Nominal <b>Tested Dilution:</b> N/A - RTU <b>Diluent:</b> N/A - RTU
<b>Soil load</b>		No soil load
<b>Carrier type, # per lot</b>		25 x 25 x 15 mm untreated Pine sapwood blocks; 10 carriers/lot
<b>Test conditions</b>		<b>Contact time:</b> 7 and 14 days <b>Temperature:</b> 25-30 (29.0) °C <b>Relative humidity:</b> 18.35-21.49%
<b>Neutralizer</b>		N/A
<b>Reviewer comments</b> (i.e., protocol deviations and amendments, retesting, control failures, etc.)		No protocol deviations or amendments reported.  <b>Subdivision G – Section 93-30; Item 4; Subsection 7 (Procedures) states: “Standardize test conidial suspensions to contain five million conidia per ml (determine spore concentration with a counting chamber) 4/ by adding sterile saline solution. This was not conducted for <i>A. niger</i>.</b>

#### IV. STUDY RESULTS

##### Control Results

Type of Control	Results	
	<i>Aspergillus niger</i> (ATCC 6275)	<i>Penicillium variable</i> (ATCC 32333)
Viable Cell Count	4.6 x 10 <sup>7</sup> CFU/mL	9.3 x 10 <sup>8</sup> CFU/mL
Initial Suspension Control	8.6 x 10 <sup>7</sup> CFU/mL	3.4 x 10 <sup>7</sup> CFU/mL
Standardized Conidial Suspension(s)	Not conducted*	Standardized to approximately 5 x 10 <sup>6</sup> CFU/mL

\*Subdivision G – Section 93-30; Item 4; Subsection 7 (Procedures) states: “Standardize test conidial suspensions to contain five million conidia per ml (determine spore concentration with a counting chamber) 4/ by adding sterile saline solution.

Wood block Mildew-Fungistat (RTU Spray; tested at nominal concentration; no soil load)

MRID	Organism(s)	Carrier No.	Untreated Control Carrier Coverage**		Lot ROJH01102020-A		Lot ROJH01102020-B	
			7 days	14 days	7 days***	14 days***	7 days***	14 days***
51679701	<i>Aspergillus niger</i> (ATCC 6275) and <i>Penicillium variable</i> (ATCC 32333)	1	75%	75%	No growth (0%)	Growth - 40%	No growth (0%)	Growth - 40%
		2	80%	80%	No growth (0%)	Growth - 45%	No growth (0%)	Growth - 65%
		3	70%	75%	No growth (0%)	Growth - 60%	No growth (0%)	Growth -70%
		4	80%	80%	No growth (0%)	Growth - 65%	No growth (0%)	Growth - 85%
		5	65%	65%	No growth (0%)	Growth - 70%	No growth (0%)	Growth - 50%
		6	70%	70%	No growth (0%)	Growth - 25%	No growth (0%)	Growth - 50%
		7	70%	75%	No growth (0%)	Growth - 35%	No growth (0%)	Growth - 40%
		8	80%	80%	No growth (0%)	Growth - 40%	No growth (0%)	Growth - 40%
		9	80%	80%	No growth (0%)	Growth - 45%	No growth (0%)	Growth - 35%
		10	90%	90%	No growth (0%)	Growth - 50%	No growth (0%)	Growth - 45%

\*\* Each untreated control carrier must be at least 50% covered with fungal growth after 7 days.

\*\*\*Visual and magnified (15X) results.

## V. STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
51356201	Mildew-Fungistat	Hard, porous surfaces (Pine sapwood blocks)	RTU Spray - 1 spray from a 12 inches (1 foot) distance on each side of the carrier, until thoroughly wet. The carriers were then lightly sprayed with the fungi conidial suspension using 3 sprays per side of the carrier using a DeVilbiss atomizer.	7 days	No soil load	N/A	<ul style="list-style-type: none"> <li>• <i>Aspergillus niger</i> (ATCC 6275)</li> <li>• <i>Penicillium variable</i> (ATCC 32333)</li> </ul>	Yes

## VI. LABEL COMMENTS

Label Date/ID: 09/10/2021 (HL version)

1. The proposed label claim that the product, **CONCROBIUM MOLD CONTROL PLUS** when used as a RTU spray, is an effective mildew/fungistat against *Aspergillus niger* (ATCC 6275) and *Penicillium variable* (ATCC 32333) on pre-cleaned and untreated indoor wood for a period of 7 days:

This claim is acceptable as it is supported by the submitted data. However, the data support uses specifically on untreated wood and not on all porous surfaces. Appropriate carrier should be tested to represent general porous surfaces. Specify throughout the label and in the directions for use that the product is intended to prevent or inhibit the growth of mildew on untreated wood materials (as well as hard, non-porous surfaces and fabrics). Remove the generic “surfaces”, “porous”, and “semi-porous” wording.

### 2. Make the following changes to the proposed label:

- a. Throughout the label,
  - i. Remove references to the product eliminating mold and mildew problems, as “problems” is too vague.
  - ii. Residual claims should specify mildewstat claims. This means brackets from “prevents/inhibits the growth of...” and mold and mildew should be removed, as these terms are not optional for residual activity. Please ensure that these claims indicate a 7 days residual period.
  - iii. Claims for outdoor uses should specify for cleaning purposes.
  - iv. Residual claims to prevent or inhibit “fungi” should specify “fungi which causes mildew”.
- b. On page 2 of 15 of the proposed label,
  - i. Qualify the following claim: “Concrobium Mold Control Plus [insert brand name] not only [kills] [eliminates 99.9% of] [existing] mold on hard, non-porous surfaces but prevents it from coming back”, with Qualifier No. 1 or delete the claim as it may be misleading as written.
- c. On page 6 of 15 of the proposed label,
  - i. Revise qualifiers “∞” and “°” to be not optional/notes to reviewer and to inform the end user what the specific uses referred to in the claims are. For example, the qualifier for “∞” should be defined as: “When used as disinfectant, mildewcide and mildewstat” and the qualifier for “°” should be defined as “When used as disinfectant and mildewstat”.
  - ii. Qualifier #1 should indicate hard, non-porous surfaces, untreated wood, and cotton fabrics.
- d. On page 7, the surface items for fungistat/mildewstat claims should only be non-porous, untreated wood, and/or fabric materials.
- e. Similarly on page 9, remove items that are porous under the directions for use, such as general porous surfaces, wallboard, concrete, masonry block, and building materials that are not wood. Please indicate that the use should be indoors.

- f. On page 9,
  - i. Remove electric or compression sprayer application as the product was not tested using such application.
  - ii. The instruction “To prevent (inhibit) (control) mold and mildew (and) (or) (disinfect)” should remove “(and) (or) (disinfect)” since the use directions for both are unique and different. To disinfect, the application is specific to distance, type of surfaces, contact time, and other conditions.
- g. On pages 9, 10, and 11, remove the direction (Step #5) that implies the treated surfaces can be painted. The residual static of the product for up to 7 days may be affected by painting over the surface.
- h. On page 12 of 15 of the proposed label,
  - i. Delete the section titled “FOGGING INSTRUCTIONS” as this application should be supported by test data. To use fogging to preclean is not realistic as cleaning is a physical activity. Additionally, “contamination control (knock down)” can be interpreted as an efficacy (public health) claim for which no data has been submitted.